ACTHERM Inc.
6F, No.18, Jhanye 2nd Rd.,
Hsinchu Science Park, Hsinchu 30078,
TAIWAN, R.O.C.
e - mail: actherm@actherm.com.tw
☎ 886 36 66 95 96
886 36 66 96 97

CE 0123

K093795

MAR 12 2010

510(k) Summary

Submitter's Identification

Actherm Inc.
6F, No.18, Jhanye 2nd Rd.,
Hsinchu Science Park, Hsinchu 30078,
Taiwan, R.O.C.
Tel : +886 3 666 9596
Fax: +886 3 666 9697

Contact Person : Richard Hsieh
Date the summary was prepared : December 04, 2009

Name of the device

Trade Name – Actherm Infrared Ear Thermometer ACT 8000R Series and Its Probe Cover medACCU 2010
Common Name – Infrared Ear Thermometer
Classification name – Clinical Electronic Thermometer (21CFR 880.2910, Product FLL)

Predicate Device Information

Actherm Infrared Ear Thermometer ACT 8000 Series and Its Probe Cover medACCU 2010
510 (k) number : K090031.

ACTHERM Inc.
6F, No.18, Jhanye 2nd Rd.,
Hsinchu Science Park, Hsinchu 30078,
TAIWAN, R.O.C.
e - mail: actherm@actherm.com.tw
☎ 886 36 66 95 96
886 36 66 96 97

CE0123

Device Description

Actherm Infrared Ear Thermometers (Model ***ACT 8000R Series***) are electronic thermometers using a thermopile as the temperature sensor. The sensor's electric signal is then calculated and displayed by a Micro-Controller. These thermometers display the temperature decimal. To compare with ACT 8000 Series, Model ***ACT 8000R Series*** has the same indication for use. ***ACT 8000R Series*** can be made with various functions, such as Dual scale, Backlight, Scan LED, W/O cover, following with the model number indicates scale switchable, with Backlight, with Scan completed indicator, without probe cover, will be added following the model number.

The infrared ear thermometer comprises: a thermopile for temperature sensing, a buzzer for sounding effect, a Micro Controller and a LCD display for calculating and displaying the target temperature digitally.

Actherm Infrared Ear Thermometers ***ACT 8000R Series*** can be combined with accessories, base, wall mount and power adapter. The base is a tray for holding probe cover box, power input, power/charge indicator, portable/ fixed probe-cover dispenser and the area for placing digital thermometer and its probe cover. For the wall mount, it can be fixed on the wall and the base can be put on this wall mount.

The system uses two 1.5V DC alkaline rechargeable batteries for the power supply and the battery power is automatically checked by the Micro-Controller and displayed in LCD if the battery is exhausted. The batteries can be recharged only when the ear thermometer ***ACT8000R*** put on the base. ***ACT 8000R*** cannot be used when recharging.

(Labeling please see Attachment 1)

Intended Use

Actherm Infrared Ear Thermometers ***ACT 8000R Series*** have the same intended use as the predicate device. They are used to measure body temperature from auditory canal. This device is intended for household and hospital use on people of all age, and is used with or without probe cover.

ACTHERM Inc.
6F, No.18, Jhanye 2nd Rd.,
Hsinchu Science Park, Hsinchu 30078,
TAIWAN, R.O.C.
e - mail: actherm@actherm.com.tw
☎ 886 36 66 95 96
886 36 66 96 97

CE 0123

Technological Characteristics

Actherm Infrared Ear Thermometers ***ACT 8000R Series*** have the same mode of operation, design principle, and biological specifications as the predicate device. ***ACT 8000R Series*** can be made with various functions, such as Dual scale, Backlight, Scan LED, W/O cover, following with the model number indicates scale switchable, with Backlight, with Scan completed indicator, without probe cover, will be added following the model number.

Comparison to 510(k) Predicate Devices

The Actherm Infrared Ear Thermometers, the ***ACT 8000R Series*** are substantially equivalent to the following digital thermometers: Infrared Ear Thermometer Model ACT 8000 Series. Its 510(k) number is K090031.

To compare with ACT 8000 Series, the Actherm Infrared Ear Thermometers ***ACT 8000R Series*** are similar in design and intended use to the predicates differing only in supplied batteries.

The ACT8000 Series use two 1.5V DC alkaline batteries and the ***ACT 8000R Series*** use two 1.5V alkaline rechargeable batteries that can be recharged only when the infrared ear thermometer ***ACT 8000R*** is put on the base. ***ACT 8000R*** cannot be used when recharging.

All products use the same temperature sensing element — a thermopile, an LCD display, Micro-Controller and a buzzer.

Substantial Equivalence

Infrared Ear Thermometers ***ACT 8000R Series***, and the claimed device are the same in intended use, essential component, sensor, power requirement, PCB circuit, software program, biological specification, performances, design principle, dimension of probe and probe cover, and are also close in electrical safety, and materials, etc. However, in these characters, the slight difference of measuring range, battery type, labeling, won't affect product safety and effectiveness.

ACTHERM Inc.
6F, No.18, Jhanye 2nd Rd.,
Hsinchu Science Park, Hsinchu 30078,
TAIWAN, R.O.C.
e - mail: actherm@actherm.com.tw
☎ 886 36 66 95 96
886 36 66 96 97

CE0123

The change is in power supply. The ACT 8000 Series use two 1.5V DC alkaline batteries and the ***ACT 8000R Series*** use two 1.5V alkaline rechargeable batteries that can be recharged only when the infrared ear thermometer ***ACT 8000R*** is put on the base. The base is a tray for holding probe cover box, power input, power/charge indicator, portable/ fixed probe-cover dispenser and the area for placing digital thermometer and its probe cover. ***ACT 8000R*** cannot be used when recharging. It has passed electrical safety performed test, therefore, it is safe for human body.

According to the description above, the two devices are substantial equivalent.

Performance Data

Actherm Infrared Ear Thermometers ***ACT 8000R Series*** meets the ASTM Standard Specification for Infrared Thermometer for Intermittent Determination of Patient Temperature (ASTM E 1965-98: 2003), as well as EN 60601-1 (IEC 60601-1), EN 60601-1-2 (IEC 60601-1-2), EN 12470-5 and ISO 10993-1, ISO 10993-5, ISO 10993-10 requirements. For all body contacting materials, the analysis has been made and the identical materials have been used in other legally marketed devices under the same use conditions.

Safety and Effectiveness

Actherm Infrared Ear Thermometer ACT 8000 and ***ACT 8000R*** and Probe Cover medACCU 2010 fulfill the testing requirements of ASTM E 1965-98, EN 60601-1 (IEC 60601-1), EN 60601-1-2 (IEC 60601-1-2) and EN 12470-5. ***ACT 8000R*** just add the function of recharge, when recharging ***ACT 8000R,*** it must be put on the base and cannot take temperature. In addition, ***ACT 8000R Series*** also meets electrical Safety performed test such as EN 60601-1 (IEC 60601-1), EN 60601-1-2 (IEC 60601-1-2), so it is safe for human body. Moreover, Infrared Ear Thermometers ***ACT 8000R Series***, and the claimed device are the same in intended use, essential component, sensor, power requirement, PCB circuit, Software program, biological specification, performances, design principle, dimension of probe and probe cover, and also close in electrical safety, and materials, etc. The clinical test results of Actherm Infrared Ear Thermometer ACT 8000 and Probe Cover medACCU 2010 conform to the requirements of ASTM E 1965-98 and EN 12470-5 that are the same performance for ***ACT 8000R Series***. The product quality is standard-guaranteed. The compliance tests demonstrate precise measuring function and the clinical accuracy of the thermometer. Therefore, these thermometers are safety and effectiveness.

ACTHERM Inc.
6F, No.18, Jhanye 2nd Rd.,
Hsinchu Science Park, Hsinchu 30078,
TAIWAN, R.O.C.
e - mail: actherm@actherm.com.tw
☎ 886 36 66 95 96
886 36 66 96 97

CE 0123

Conclusion

Actherm Infrared Ear Thermometers ***ACT 8000R Series*** have the same intended use, principles of operation, and similar technological characteristics as predicate devices. Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Actherm Infrared Ear Thermometers ***ACT 8000R Series*** are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Richard Hsieh
General Manager
Actherm, Incorporated
6F, No. 18 Jhanye 2nd Road Hsinchu Science Park
Hsinchu
China Taiwan 30078

MAR 12 2010

Re: K093795
Trade/Device Name: Actherm Infrared Ear Thermometer ACT 8000R Series and Its Probe Cover medACCU2010
Regulation Number: 21CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 4, 2010
Received: February 16, 2010

Dear Mr. Hsieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ACTHERM Inc.
6F, No.18, Jhanye 2nd Rd.,
Hsinchu Science Park, Hsinchu 30078,
TAIWAN, R.O.C.
e - mail: actherm@actherm.com.tw
☎ 886 36 66 95 96
886 36 66 96 97

CE 0123

Indication for Use

510(k) Number (if known) : K093795

Device Name : Actherm Infrared Ear Thermometer ACT 8000R Series and Its Probe Cover medACCU2010

Indication For Use :

Actherm Infrared Ear Thermometers ***ACT 8000R Series*** are used to measure body temperature from auditory canal. This device is intended for household and hospital use on people of all age, and is used with or without probe cover medACCU2010.

Prescription Use _____ AND/OR Over-The-Counrter Use ___x___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093795